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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,748	06/30/2003	Narendra S. Yadav	CL1944USNA	4485

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WILMINGTON, DE 19805

EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/611,748

Applicant(s)

YADAV, NARENDRA S.

Examiner

Cathy K. Worley

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 5-10, 13, and 21-26, drawn to a gene silencing site-specific recombination system comprising a first recombinase element having the general structure P1-R, wherein P1 is a first promoter and R is a recombinase coding sequence and 3' region; and a second gene silencing-recombinase element having the general structure: RS-X-RS*-Y, classified in class 435 subclass 320.1, for example.
- II. Claims 4-6, 11, 13, and 21-26, drawn to a gene silencing site-specific recombination system comprising a first recombinase element having the general structure P1-R, wherein P1 is a first promoter and R is a recombinase coding sequence and 3' region; and a second gene silencing-recombinase element having the general structure: P2-TS-RS-Z-RS-TS_{INV}-polyA, classified in class 536 subclass 23.1, for example.
- III. Claims 12-13 and 21-26, drawn to a gene silencing site-specific recombination system comprising a first recombinase element having the general structure P1-R, wherein P1 is a first promoter and R is a recombinase coding sequence and 3' region; and a second gene silencing-recombinase element having the general structure: P2-TS-

5'Intron-RS-STP-RS-3'Intron-TS_{INV}-polyA, classified in class 536 subclass 24.1, for example.

- IV. Claims 27-34, drawn to a method for silencing a target gene, comprising introducing into a plant cell comprising a target gene, a gene silencing construct wherein expression of the recombinase results in translation of the target sequence and the production of double-stranded target sequence RNA, classified in class 800 subclass 285, for example.
- V. Claims 35-38, drawn to a method for effecting systemic gene silencing in a plant comprising providing constructs comprising 3 elements, providing a plant having a target gene, and chemically inducing a promoter from one of the elements to cause inversion or excision of elements between recombinase sites, classified in class 800 subclass 278, for example.

Claims 14-20 are not included in any groups because claims 14 and 18 depend from themselves, and therefore it is unclear what limitations are included in these claims. Claims 15-17 and 19-20 depend from claims 14 and 18, and therefore the limitations in these claims are also unclear.

Inventions I-V are patentably distinct. Each of these inventions comprises a unique combination of nucleic acid fragments in different orientations. Each of

these combinations results in different functionality and comprises unique nucleotide sequences. Because the function and structure of each of these combinations is different, these are patentably distinct inventions.

A search for each of these inventions will require searching the literature for the particular combination of nucleic acid fragments and functional elements recited in the particular invention. These searches are not coextensive, and therefore, it would be an undue burden to examine these inventions together.

If one of the groups selected from group I, IV or V is elected, there will be an additional election of species.

Group I will require two separate elections of species. Group I contains claims directed to a system comprising a second element having the general structure: RS-X-RS*-Y; wherein X and Y are selected from a list of specified DNA fragments. The following are the patentably distinct species of X included in the list:

- A) P2_{INV}
- B) TS_{INV}-P2_{INV}
- C) 5'Intron- TS_{INV}-P2_{INV}

The following are the patentably distinct species of Y included in the list:

- D) TS-P3_{INV}
- E) TS_{INV}-polyA

F) 3'Intron- TS_{INV}-polyA.

The species are independent or distinct because each species has a unique structure and a unique function.

If Applicant elects Group I, then Applicant must elect ONE SPECIES from A, B, or C, above; and ONE SPECIES from D, E, or F, above. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each list for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-2 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Groups IV and V contain claims directed to a system comprising a second element having the general structure selected from a list of specified combinations

of DNA fragments. The following are the patentably distinct species of combinations included in the list:

- A) RS-P2_{INV}-RS-TS-P3_{INV}
- B) RS-TS_{INV}-P2_{INV}-RS-TS_{INV}-polyA
- C) RS-5'Intron-TS_{INV}-P2_{INV}-RS-3'Intron-TS_{INV}-polyA
- D) P2-TS-RS-STP-RS-TS_{INV}-polyA
- E) P2-TS-5'Intron-RS-STP-RS-3'Intron-TS_{INV}-polyA

The species are independent or distinct because each species has a unique structure and a unique function.

If Applicant elects Group IV or V, then Applicant must elect ONE SPECIES from A, B, C, D, or E, above. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each list for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 34, in its entirety, is generic for group IV; claim 35, in its entirety, is generic for group V.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner can normally be reached on M-F 8:30 - 5:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CKW

June 23, 2006


ANNE MARIE GRUNBERG
SUPERVISORY PATENT EXAMINER